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| 10/790,318 | 06/01/2004 | Michael F. Oyaski | MFO 04060 | 9279 |

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| EXAMINER |
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BOGART, MICHAEL G

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| ART UNIT | PAPER NUMBER |
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09/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/790,318 | Applicant(s) OYASKI, MICHAEL F. | |
| | Examiner MICHAEL G. BOGART | Art Unit 3761 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17, 18 and 20-23 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 15, 17, 18 and 20-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections – 35 US § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 14, 15, 17, 18 and 20-23 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 14 recites the limitation where the bodysuit member has a size and shape which allows aeration with intermittent moist treatment without additional exposure to contaminants. Claim 14 further recites a texture that permits alternating circulation of a gaseous fluid and a liquid fluid. There is no support in the specification for these functional limitations. Applicant's specification only provides support for a medium that is at least one of a liquid and a gas (col. 6, lines 1-3). Applicant's specification does not provide any support for the size and shape of the body or its inner texture permitting either intermittent or alternating treatment with or circulation of a gaseous fluid and a liquid fluid. Applicant's specification merely indicates that the textured inner surface permits circulation (page 7, lines 10-24). Claims 15, 17, 18 and 20-23 are rejected for depending from a claim that is not enabled.

Art Unit: 3761

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 14, 15, 17, 18 and 20-23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Eriksson (US 5,152,757 A) in view of Lockwood *et al.* (US 6,685,681 B2; hereinafter “Lockwood”).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Regarding claim 14, Eriksson teaches a device capable of both treating and promoting healing of damaged body tissue, said device comprising;

a bodysuit member (60) having each of a predetermined size and a predetermined shape which is capable of allowing aeration with intermittent moist treatment without additional exposure to contaminants, said bodysuit (60) having an outer surface facing atmosphere and an inner surface facing a body area of a person to be treated; and

at least three fluid transfer means (88) sealingly engaged with said bodysuit space and disposed in fluid communication with a space located between said inner surface of said bodysuit

Art Unit: 3761

and said damaged body tissue, a first one of said fluid transfer means that is capable of allowing communication of said gaseous fluid and a second one of said fluid transfer means that is capable of allowing communication of said liquid fluid to such space disposed between said inner surface of said bodysuit and such damaged body tissue thereby enabling such damaged body tissue to be effectively treated and healed in controlled environmental conditions without requiring removal of said bodysuit member and a third one of said fluid transfer means that is capable of removing each of said gaseous and liquid fluids from said bodysuit (60)(see figs. 9 & 15, below)(col. 20, lines 62-65; col. 21; lines 51-68)(abstract).

Eriksson discloses a bodysuit with separate chambers each having at least two ports (88). One of the chambers could be filled with a gas through one of its ports, another chamber could be filled with a liquid through one of its ports and a third chamber could be filled with a liquid-gas mixture that could be emptied from one of that chamber's ports (see fig. 15).

Eriksson does not expressly teach that the inner surface of the bodysuit member is textured.

Lockwood teaches a vacuum bandage that includes a wound-contacting layer (20) with a texture (28) which channels fluids (see fig. 16, below).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to add the textured channels of Lockwood to the system of Eriksson in order to provide fluid flow channels even in portions of the system that are compressed by a wearer's bodyweight, so fluid can circulate.

Where a claimed improvement on a device or apparatus is no more than "the simple substitution of one known element for another or the mere application of a known technique to a

Art Unit: 3761

piece of prior art ready for improvement," the claim is unpatentable under 35 U.S.C. § 103(a). *Ex Parte Smith*, 83 USPQ.2d 1509, 1518-19 (BPAI, 2007)(citing *KSR v. Teleflex*, 127 S.Ct. 1727, 1740, 82 USPQ2d 1385, 1396 (2007)). Accordingly, Applicant claims a combination that only unites old elements with no change in the respective functions of those old elements, and the combination of those elements yields predictable results; absent persuasive evidence that the modifications necessary to effect the combination of elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. § 103(a). *Ex Parte Smith*, 83 USPQ.2d at 1518-19 (BPAI, 2007)(citing *KSR*, 127 S.Ct. at 1740, 82 USPQ2d at 1396). Accordingly, since the applicant[s] have submitted no persuasive evidence that the combination of the above elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. § 103(a) because it is no more than the predictable use of prior art elements according to their established functions resulting in the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement.

Eriksson and Lockwood do not expressly disclose the functional limitations concerning how the device is sized, shaped or textured to permit alternating or intermittent application of gas and liquid with out requiring removal of the bodysuit member.

While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (The absence of a disclosure in a prior art reference relating to function did not defeat the Board's finding of anticipation of claimed apparatus because the limitations at issue were found

Art Unit: 3761

to be inherent in the prior art reference); see also *In re Swinehart*, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971); *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original).

The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103. “The inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness.” *In re Napier*, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995) (affirmed a 35 U.S.C. 103 rejection based in part on inherent disclosure in one of the references). See also *In re Grasselli*, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed. Cir. 1983).

Eriksson and Lockwood teach a bodysuit inherently sized and shaped such that they permit, or at least do not preclude alternating application of gas and liquid without removing the bodysuit member. For example, a source of liquid can be attached to one of the Eriksson’s inlet ports (28) and can be replaced with a source of gas, all while the bodysuit remains attached to a wearer.

Further regarding claim 14, Lockwood teaches a texture (28) that permits or at least does not preclude alternating circulation of gas and liquid.

Regarding claim 15, Eriksson teaches transparency (col. 2, line 34).

Regarding claim 17 and 18, Eriksson teaches multiple ports (88)(fig. 15).

Regarding claims 20-22, Eriksson teaches that the fluid is a liquid medication, painkiller or both (col. 6, lines 55-68).

Art Unit: 3761

Regarding claim 23, Eriksson teaches a bodysuit member (60) that covers an entire body, see figure 15, *infra*.

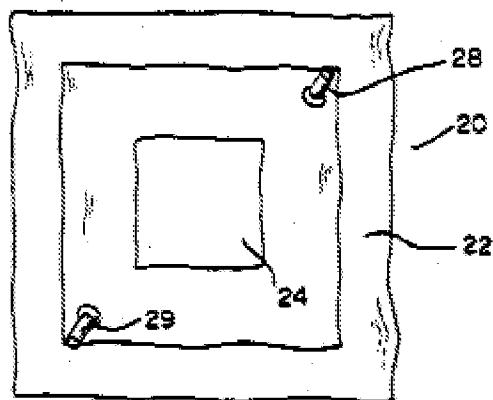
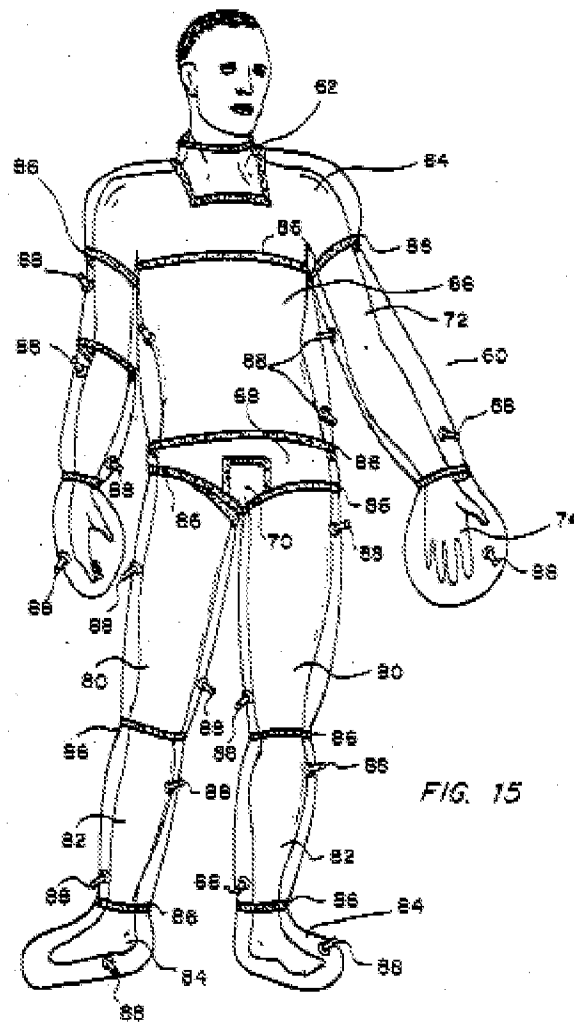


FIGURE 9

Art Unit: 3761



Art Unit: 3761

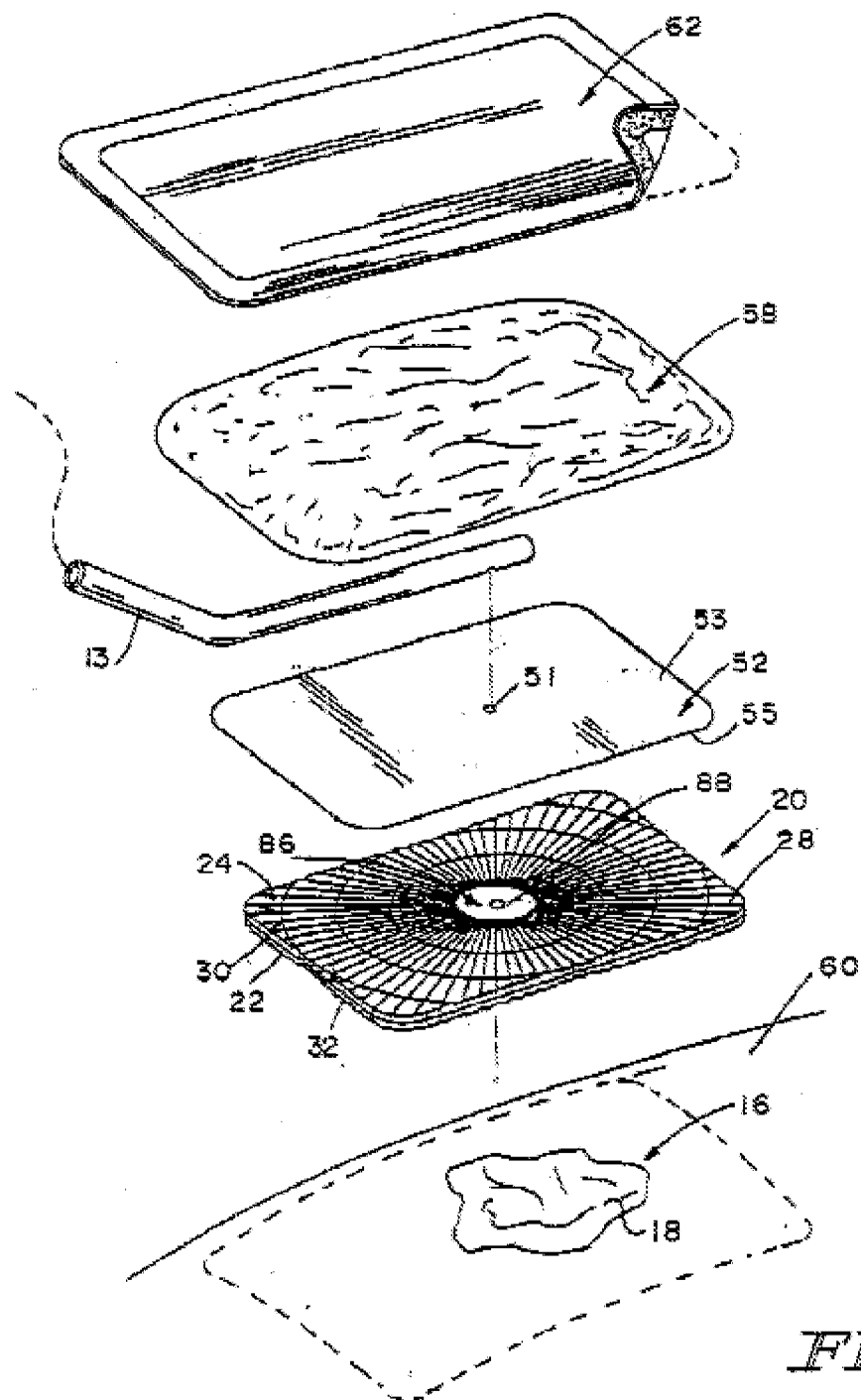


FIG 16

Response to Arguments

Applicant's arguments filed 09 May 2008 have been fully considered but they are not persuasive.

3. Regarding the rejections under 35 USC § 112(1), applicants assert that the Examiner's comment with respect to the textured inner surface was in error since this was disclosed in the parent case. This argument is not persuasive because the original specification of parent US application 09/874,539 has been reviewed and it merely indicates that the textured inner surface permits circulation (page 7, lines 16-19). It provides no specific support for the more detailed functional limitations as claimed.

4. Regarding the rejections under 35 USC § 103, applicants assert that newly amended claim 14 has at least three fluid transfer means, one for communicating with a gas, a second for communication with a fluid and a third for removing each of said gaseous and liquid fluids from the bodysuit. This argument is not persuasive, because the combined structure of the bodysuit has more than 3 ports (see fig. 15). Each chamber has at least one port. One chamber/subsection could communicate with a gas, another section could communicate with a liquid and a third section could be filled with both. Thus the overall bodysuit would have a gas port, a liquid port and a gas/liquid evacuation port.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3761

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL G. BOGART whose telephone number is (571)272-4933. The examiner can normally be reached on M-F, 10-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/790,318

Page 12

Art Unit: 3761

/Michael G. Bogart/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761